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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,281

04/13/2006

Joel Richard

065691-0410

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22428 7590 08/19/2008  
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EXAMINER

BUIE, NICOLE M

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

08/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/554,281	<b>Applicant(s)</b> RICHARD ET AL.	
	<b>Examiner</b> NICOLE M. BUIE	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 29-57 is/are pending in the application.
- 4a) Of the above claim(s) 48-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20051025/20060413/20060522</u> .                              | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of **Group I, claims 29-47** in the reply filed on 06/20/2008 is acknowledged.

The traversal is on the ground(s) that "the Restriction Requirement was made under 35 USC§ 121 and 372" (P2). Additionally, the traversal is on the ground(s) that claims to different categories of invention will be considered to have unity of invention when the claims are drawn to "[a] product and a process of use of said product" (P2). Additionally, the traversal is on the ground(s) that the restriction requirement between Group I, II, and III is improper (P2). This is not found persuasive because the special technical feature of the block copolymer comprising at least one CO<sub>2</sub>-philic block and at least one biocompatible block was shown to be disclosed in Goetz et al. (US 6,586,530).

The requirement is still deemed proper and is therefore made FINAL.

**Claims 48-57** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Information Disclosure Statement***

The information disclosure statement filed 10/25/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the non-patent

documents EP 0706821 and WO 97/18234 and all of the non-patent literature documents have not been considered, since no copies of the said documents have been provided.

The information disclosure statement filed 04/13/2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the non-patent literature Heller et al. "Steric Protection of Hydrophobic Colloidal Particles by Adsorption of Flexible Macromolecules," Journal of Chemical Physics, 1954, Vol. 22, p. 2278 has not been considered, since no copy of the said document has been provided.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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**Claims 29-33 and 37-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al. (EP 0784506 B1) in view of Mueller et al. (US 5,115,056) as evidenced by Pathak et al. (US 2002/0151650).

**Regarding claims 29, 30, 32, 33, and 37-47**, Benoit et al. discloses a method for dispersing a water soluble or hydrophilic substance (i.e. pharmaceutical compositions, such as somatostatin, calcitonin, brain derived neurotrophic factor) in a supercritical fluid (i.e. carbon dioxide) comprising adding a surfactant to the fluid ([0009],[0026], [0028]). Benoit et al. also discloses copolymers with acrylic or methacrylic acid [0024].

However, Benoit et al. does not disclose the surfactant is a block copolymer comprising at least one CO<sub>2</sub>-philic block and at least one nonionic hydrophilic block. Mueller et al. teaches a block copolymer in a hydrogel comprising at least one CO<sub>2</sub>-philic block (i.e. (1,1,2,2-tetrahydroperfluorodecyl acrylate) and at least one nonionic hydrophilic block (i.e. (1,1,2,2-tetrahydroperfluorodecyl acrylate) where the monomers are able to polymerize with each other) (C8/L67-C9/L2). Additionally, Mueller et al. teaches the block copolymer where 1—80 wt% by weight of a vinyl-telechelic polyether and 90-20 wt% of the fluorinated monomer (C4/L8-23). Benoit et al. and Mueller et al. are analogous art concerned with the same field of endeavor, namely coating materials comprising polymers which are biocompatible for biomedical applications. It would have been obvious to one of ordinary skill in the art at the time of invention to use the block copolymer of Mueller et al. in the process of Benoit et al., and the motivation to do so would have been as Mueller et al. suggests that the block copolymers are flexible, clear, wettable, and oxygen permeable hydrogels, which are useful in biomedical

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applications (C3/L60-65). As evidenced by Pathak et al., a biologically active agent may be incorporated in a hydrogel [0025].

**Regarding claim 31**, Benoit et al. discloses the method wherein the supercritical fluid is CO<sub>2</sub> comprising an entrainer in an amount of less than 5% [0026].

**Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al. (EP 0784506 B1) in view of Mueller et al. (US 5,115,056) as evidenced by Perman et al. (US 5,340,614).

**Regarding claim(s) 34**, modified Benoit et al. does not disclose the method wherein a minimum solubility of the block copolymer is 0.05% w/w at least one defined temperature between 0°C and 100°C and at least one defined pressure, that is greater than the supercritical pressure of CO<sub>2</sub> and less than 70 MPa. As the stability of the polymer in supercritical fluid is variable that can be modified by adjusting said solubility as evidenced by Perman et al. (C6/L21-32), the precise solubility would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, solubility, and the motivation to do so would have been to obtain desired stability of the polymer (*In re Boesch*, 617 F.2d. 272,205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05.

**Claims 35 and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al. (EP 0784506 B1) in view of Mueller et al. (US 5,115,056) as applied to claim 29 above, and further in view of Stefely et al. (US 6,126,919).

**Regarding claims 35 and 36**, modified Benoit et al. discloses the method of claim 29 as shown above. Benoit et al. further discloses a copolymer [0024].

However, modified Benoit et al. does not disclose the number average molar mass of the copolymer. Stefely et al. teaches a number-average molecular weight of the polymer is no greater than about 1800 (C4/L54-60). Modified Benoit et al. and Stefely et al. are analogous art concerned with the same field of endeavor, namely pharmaceutical drug deliver systems. It would have been obvious to one of ordinary skill in the art at the time of invention to use the number average molecular weight of the polymer of Stefely et al. in the method of modified Benoit et al., and the motivation to do so would have been as Stefely et al. suggests to provide rapid biodegradation of the polymer (C4/L54-60).

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE M. BUIE whose telephone number is (571)270-3879. The examiner can normally be reached on Monday-Thursday with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571)272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo, Ph.D./  
Supervisory Patent Examiner, Art Unit 1796  
14-Aug-08

/N. M. B./  
Examiner, Art Unit 1796  
8/7/2008